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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/819,669

03/17/1997

THIERRY BOON

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1995

24972 7590 03/20/2009
FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER

GAMBEL, PHILLIP

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 08/819,669	Applicant(s) BOON ET AL.	
	Examiner Phillip Gambel	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 183-191 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 183-191 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Decision on Appeal Under 35 USC 134 by the Board of Patent Appeals and Interferences (BPAI), mailed 01/16/2009, is acknowledged.
2. Claims 183-191 are pending.
3. The following New Grounds of Rejection have been set forth herein.
4. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornam, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 183-191 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,843,448 (see 892, mailed 03/28/2001).

Although the claims are not the same, the patented claims, drawn to MAGE-1 tumor rejection antigen precursors and immunogenic compositions, anticipate the instant claims, drawn to MAGE tumor rejection antigen precursor proteins and compositions. It has been well known by the ordinary artisan for decades that vaccines are immunogenic and often comprise an adjuvant to increase the immunogenicity of the immunogenic or vaccine composition of interest.

Further, it is noted that SEQ ID NO: 8 of instant USSN 08/819,669 is the same as SEQ ID NO: 1 disclosed in Example 5 of U.S. Patent No. 5,843,448 (e.g., see Example 5 on columns 7-8 of U.S. Patent NO. 5,843,448).

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Also, note that SEQ ID NO: 8 of the instant USSN 08/819,669 is described as SEQ ID NO: 8 which is a nucleic acid sequence encoding MAGE-1 (see Brief Description of the Sequences on page 10 of the instant specification). MAGE-1 is the subject of the patented claims and Example 5 of U.S. Patent No. 5,843,448.

Therefore, the instant claims and patented claims can anticipate or render obvious one another based upon either MAGE-1 or a MAGE protein comprising or hybridizing with SEQ ID NO: 8.

In addition, the following facts are noted.

A) Applicant filed a terminal disclaimer on 12/12/2006 supporting the obviousness of the instant claims over the claims of U.S. Patent No. 5,843,448.

B) In the Petition To Withdrawn Terminal Disclaimer, filed 05/02/2008, applicant noted the following.

FACTS

On December 6, 2006, the Examiner rejected the claims of this application on double patenting grounds, in view of U.S. Patent No. 5,843,448. The '448 patent issued with the incorrect assignees on its face. The record of its prosecution indicates, however, that the patent was co-owned: As such an obviousness-type double patenting rejection, and a terminal disclaimer are not appropriate. Please see the assignment documents from the parent application, i.e., U.S. Patent No. 5,541,104, indicating that there are two assignees, one of whom (Cornell Research Foundation, Inc), is NOT an assignee of the current application. In short, co-ownership does not exist.

When there is no co-ownership, a terminal disclaimer is not proper, because an obviousness type double patenting rejection is not proper.

In view of the foregoing, it is requested that the Terminal Disclaimer filed over U.S. Patent No. 5,843,448, be WITHDRAWN.

It is noted that the Petition to Withdraw the Terminal Disclaimer, filed 12/12/2006, was granted and mailed on 07/21/2008.

However, applicant's following statement from the Petition is incorrect.

When there is no co-ownership, a terminal disclaimer is not proper, because an obviousness type double patenting rejection is not proper.

While a terminal disclaimer is not proper between this application and U.S. Patent No. 5,843,448, an obviousness-type double patenting rejection is still deemed proper.

An obvious-type double patenting rejection is proper when there is at least one common inventor, even if there is no common ownership. For example, see Chart II-B in MPEP 804 (follow the center path). Establishing a lack of common ownership removes the option of overcoming the obviousness-type double patenting rejection via a terminal disclaimer, but it does not overcome the obviousness-type double patenting rejection.

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C) The Decision on Appeal Under 35 USC 134 by the Board of Patent Appeals and Interferences (BPAI), mailed 01/16/2009, provides for the consideration of obviousness-type double patenting between the instant application and U.S. Patent No. 5,843,448 to be addressed in the instant application. See page 6 of the Decision as follows.

Should the double-patenting rejection have been withdrawn?

Fortunately, to the extent the examiner considers these questions unanswered on the present record, he has tools at his disposal to compel answers, including reinstating the double-patenting rejection or seeking additional evidence¹⁸ regarding the inventorship. The Board, however, lacks a basis in the record to pursue any of these possibilities.

6. Claims 183-191 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,495,074.

Although the claims are not the same, the patented claims, drawn to MAGE-4 tumor rejection antigens and compositions, anticipate the instant claims, drawn to MAGE tumor rejection antigen precursor proteins and compositions. It has been well known by the ordinary artisan for decades that vaccines are immunogenic and often comprise an adjuvant to increase the immunogenicity of the immunogenic or vaccine composition of interest.

Further, it is noted that nucleic acids encoding MAGE-4 were identified, at least in part, on the basis of hybridizing to the 2.4 kb

For example, see page 48 of the instant specification or column 2 of U.S. Patent No. 7,495,074.

Example 30

The cDNA coding for mage 4 was identified from a sample of the human sarcoma cell line LB23-SAR. This cell line was found to not express mage 1, 2 or 3, but the mRNA of the cell line did hybridize to the 2.4 kb sequence for mage 1. To study this further, a cDNA library was prepared from total LB23-SAR mRNA, and was then hybridized to the 2.4 kb fragment. A cDNA sequence was identified as hybridizing to this probe, and is identified hereafter as mage 4.

Note that the 2.4 kb probe is drawn to MAGE-1, which is encoded by SEQ ID NO: 8 (e.g., see Examples 20-35 of the instant application and U.S. Patent No. 7,495,074)

Given that MAGE-1 probe hybridizes to the cDNA encoding MAGE 4, the patented claims drawn to MAGE -4 would anticipate the instant claims.

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7. Claims 183-191 are directed to an invention not patentably distinct from claims 1-8 of commonly assigned U.S. Patent No. 7,495,074 for the reasons above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No., discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

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8. No claim allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/
Primary Examiner
Technology Center 1600
Art Unit 1644
March 5, 2009

/Eileen B. O'Hara/
Supervisory Patent Examiner
Art Unit 1644

/Jean C. Witz/
Quality Assurance Specialist
Technology Center 1600

/JOHN L. LEGUYADER/
Director, Technology Center 1600